

REMARKS

Upon entry of the current amendment, claims 1-44 will be pending for consideration.

In the present communication, claim 1 has been amended and new claims 40-44 have been added.

The outstanding Office action has stated that claims 16-39 are allowed.

The outstanding Office action states that claim 8 would be allowable if rewritten to incorporate all the limitations of its base claims. The subject matter of claim 8 is presented in new claim 42.

The amendment and newly added claims are supported by the specification as originally filed.

Support for amended claim 1 can be found in the specification, at, for example: page 4, paragraph 14; page 6, paragraph 27; and page 7, paragraph 31.

Support for newly presented claims 40 and 41 can be found, e.g., in original claims 2 and 13.

Support for newly presented claims 43 and 44, which depend from amended claim 1, can be found in the specification, at, for example: page 6, paragraph 27; and page 7, paragraph 31.

Reconsideration and allowance of the amended and newly presented claims, in view of the following remarks, are respectfully requested.

35 U.S.C. §102

In the Office Action, claim 1 was rejected under 35 U.S.C. §102 as being anticipated by Cawood et al. (U.S. Patent No. 4,043,328, "Cawood").

The rejection is overcome by amendment to claim 1. Amended claim 1 recites a medical device comprising:

an adhesive backing operably disposed on said sheet, proximate said aperture, wherein the adhesive backing secures the sheet, proximate said aperture, to an area surrounding the genitalia . . .

Cawood fails to identically describe a medical device or a medical drape having an adhesive backing proximal to an aperture that allows the drape to be secured to an area around the genitalia.

Cawood is directed to a disposable unitary urological drape having a finger cot that can be used to palpitate the prostate gland of a male patient during an adenomectomy (i.e., removal of a (prostate) gland; column 1, lines 45-50). The urological drape described by Cawood has an opening 19 to receive the glans penis and scrotum (column 1, lines 45-50); a finger cot or sheath 16 (below opening 19) with an annular cover 18 extending about the cot concealing a coating of pressure sensitive adhesive for securing the drape in the general area of the perineum (column 2, lines 65-68); and a protective strip 17 having pressure sensitive adhesive located along the upper edge portion of the sheet (column 1, lines 63-65). Cawood does not identically describe a medical device or a medical drape having an adhesive proximal to an aperture that allows the drape to be secured to an area around the genitalia. Thus, the rejection of claim 1 as anticipated by Cawood is overcome, and Applicants request that this rejection be withdrawn.

35 U.S.C. §103

Fenwick and Cawood: Claim 1

Claim 1 stands rejected under 35 USC §103(a) as being unpatentable over Fenwick (U.S. Patent No. 5,445,165) in view of Cawood.

The rejection is overcome by amendment to claim 1. Fenwick and Cawood, taken alone or in combination, do not teach all the elements of amended claim 1. Amended claim 1 recites a medical device comprising:

an adhesive backing operably disposed on said sheet, proximate said aperture, wherein the adhesive backing secures sheet, proximate said aperture, to an area surrounding the genitalia...

The primary reference, Fenwick, is directed to a medical drape having an upper sheet section and lower sheet section, wherein the lower sheet section has an upper and lower fenestration, wherein a filter and a drain are affixed over the lower fenestration (column 2, lines 35-40). Fenwick also describes adhesive strips 38 that are positioned on

the drape a significant distance from upper fenestration 13. Fenwick identifies adhesive strips 46, but these do not constitute an adhesive backing as recited in claim 1. Specifically, the Fenwick reference fails to describe or suggest a medical drape comprising adhesive proximal to the fenestration that allows the drape to be secured to an area around the genitalia, as recited in amended claim 1.

The Cawood reference has been discussed above, and has been shown to not identically teach the subject matter of amended claim 1. Similarly, the Cawood reference fails to remedy the shortcomings of Fenwick with respect to the obviousness rejection. In specific, the Cawood reference (as with Fenwick) also does not teach or suggest an adhesive backing that secures a sheet, proximate an aperture, to an area surrounding the genitalia, as recited in amended claim 1.

As a result, Fenwick or Cawood, taken alone or in combination, do not describe a medical device having all the features of amended claim 1. The rejection of claim 1 under 35 U.S.C. §103 has been overcome and can be withdrawn.

Fenwick, Cawood, and Taylor: Claims 2-3, 5, 9-10 and 13

Claims 2-3, 5, 9-10, and 13 stand rejected under 35 USC §103(a) as being unpatentable over Fenwick, Cawood, and further in view of Taylor (U.S. Patent No. 5,419,343).

The rejection is overcome by amendment to claim 1, upon which claims 2-3, 5, 9, 10, and 13 depend.

Upon entry of the current amendment, claims 2-3, 5, 9-10, and 13, which depend directly or indirectly from amended claim 1, will include all of the features of amended claim 1.

The teachings of Fenwick and Cawood have previously been discussed to not teach or suggest the subject matter of amended claim 1.

Taylor fails to remedy the shortcomings of the Fenwick and Cawood references with respect to the claimed subject matter. Taylor is directed to an arthroscopy drape and collection pouch, wherein the pouch is connected to a fenestration through which a patient's limb can extend through for an arthroscopy procedure (see Abstract). Like

Fenwick and Cawood, Taylor also does not teach or suggest an adhesive backing proximal to an aperture as recited in amended claim 1. As a result, Fenwick, Cawood, and Taylor do not describe a medical device having all the elements recited in claim 1, or in any of claims 2, 3, 5, 9, 10, or 13, which depend on claim 1. The rejection of claims 2, 3, 5, 9, 10, or 13, is overcome and should be withdrawn.

Fenwick, Cawood, and Neal: Claims 4 and 11-12

Claims 4 and 11-12 stand rejected under 35 USC §103(a) as being unpatentable over Fenwick, Cawood, and further in view of Neal (U.S. Patent No. 4,570,628).

The rejection is overcome by amendment to claim 1, upon which claims 4 and 11-12 depend.

Upon entry of the current amendment, claims 4 and 11-12, which depend directly or indirectly from amended claim 1, will include all of the limitations of amended claim 1.

Fenwick, Cawood, and Neal, taken alone or in combination, do not teach all the elements of amended claim 1, or of claims 4 and 11-12, which depend on claim 1.

Fenwick and Cawood are discussed above, and shown to fail to teach or suggest the subject matter of amended claim 1.

The Neal reference fails to remedy the shortcomings of Fenwick and Cawood.

Neal describes a surgical drape with a collection pouch that has volumetric measuring means (column 1, lines 60-65). However, there is no description of an adhesive backing, or any sort of adhesive for that matter, in Neal, as recited in amended claim 1.

Fenwick, Taylor, or Neal, taken alone or in combination, fail to describe a medical device having all the features of claim 1, and therefore fail to teach or suggest the subject matter of claims 4, 11, and 12, which depend from claim 1. The rejection of claims 4 and 11-12 as obvious over the cited references should therefore be withdrawn.

Fenwick, Cawood, and Baker: Claims 6-7

Claims 6 and 7 stand under 35 USC §103(a) as being unpatentable over Fenwick, Cawood, and further in view of Baker (U.S. Patent No. 5,979,450).

The rejection is overcome by amendment to claim 1, upon which claims 6 and 7 depend.

Upon entry of the current amendment, claims 6 and 7, which depend from amended Claim 1, will include all of the limitations of amended claim 1. Accordingly, Applicants submit that Fenwick, Cawood, and Baker, taken alone or in combination, do not teach all the elements of Claims 6 and 7.

Fenwick and Cawood are discussed above, and shown to fail to teach or suggest the subject matter of amended claim 1.

The Baker reference fails to remedy the shortcomings of Fenwick and Cawood.

The Baker reference is not seen to describe an adhesive proximate to an aperture, or any arrangement that would allow the sheet to be adhered to the genital area as recited in amended claim 1.

Fenwick, Cawood, or Baker, taken alone or in combination fail to teach or suggest a medical device as recited in amended claim 1, or in claims 6 or 7, and the rejection of claims 6 and 7 as obvious over Fenwick, Cawood, and Baker, should be withdrawn.

Fenwick, Cawood, and Thomalla: Claims 14-15

Claims 14 and 15 stand rejected under 35 USC §103(a) as being unpatentable over Fenwick, Cawood, and further in view of Thomalla (U.S. Patent No. 5,388,593).

The rejection is overcome by the current amendment to claim 1, upon which claims 14 and 15 depend.

Upon entry of the current amendment, Claims 14 and 15, which depend directly or indirectly from amended claim 1, will include all of the limitations of amended claim 1. Accordingly, Applicants submit that Fenwick, Cawood, and Thomalla, taken alone or in combination, do not teach all the elements of claims 14 and 15.

Fenwick and Cawood are discussed above, and are shown to fail to teach or suggest the subject matter of amended claim 1.

The Thomalla reference fails to remedy the shortcomings of Fenwick and Cawood.

Thomalla describes a surgical drape having adhesive strips 34 and 36 (column 4, lines 30-40) located at the upper end 14 and lower end 16, respectively, of the drape. Figure 1 of Thomalla shows adhesive strips 34 and 36 and adhesive tabs 38, none of which is proximal to aperture 50. Therefore, Thomalla does not specifically teach or suggest an adhesive backing that is proximate to the aperture, or any arrangement that would allow the sheet to be adhered to the genital area as recited in amended claim 1.

Overall, Fenwick, Cawood, or Thomalla, taken alone or in combination, do not describe a medical device having all the elements as described in amended claim 1, or in claim 14 or 15, which depend on claim 1. The rejection of claims 14 and 15 over the cited combination of references should be withdrawn.

Fenwick, Cawood, and Taylor: new Claim 40

Applicants present new claim 40, which includes the subject matter of claims 1 and 2 prior to the current amendment. Applicants traverse the rejection of previous claim 2 (newly presented claim 40) as obvious in view of Fenwick, Cawood, and Taylor.

Claim 40 recites a medical device comprising:

- a sheet of flexible material having an aperture of a predetermined size through which a body orifice may be accessed with a probe,
- an adhesive backing operably disposed on said sheet, proximate said aperture;
- a finger cot disposed on said sheet; and
- a pouch disposed on said sheet and sized to receive fluids discharged from the orifice.

A *prima facie* obviousness rejection requires that prior art includes a motivation for one of skill to modify prior art references in a manner that would have caused the artisan to arrive at claimed subject matter. Under the law, it is not sufficient to merely identify different elements from among the prior art and then pick and choose only certain of those elements from among the entirety of separate teachings, then conclude that the combination would have been obvious.

According to the Office action: the Fenwick reference comprises “what appears to be a pouch portion.” The Office action elsewhere regards Fenwick as disclosing a “funnel shape.” Further according to the Office action, Taylor teaches “a medical device comprising a pouch 110 and a stiffener.” The Office action concludes that it would have been obvious that the pouch and stiffener as taught by Taylor could be substituted for the funnel shape disclosed by Fenwick, based on the conclusion that “the two devices are interchangeable.”

Applicants traverse this basis of rejection as unsupported, as lacking a showing of motivation to select and combine the different elements of the cited references in a way that would arrive at the subject matter of claim 2 (now claim 40).

Fenwick or Cawood describe drapes used in urology procedures. Taylor describes a drape used for arthroscopy procedures. The different drapes are intended for different applications, and are shown to include various components for performing different functions. As described and illustrated, the drapes are used differently and are situated differently on a patient’s body.

For example, see, e.g., Figure 1 of Fenwick and Figures 1, 2, 5, and 6 of Taylor. Figure 1 of Fenwick shows the use of the Fenwick drape, wherein a drape having a funnel is placed over or attached to both of a patient’s horizontal legs so the drape extends between the legs to encompass the entire area between the horizontal legs of the patient. The funnel is positioned in the center of this area to collect fluids.

In contrast, the Taylor figures show a pouch to collect fluids, wherein the pouch has two apertures (for a single leg) that are positioned to locate the pouch along a portion of a single horizontally extended leg. The drape in the Taylor figure is illustrated as hanging vertically as opposed to the relatively horizontal drape of Fenwick.

According to the Office action, the pouch structure of Taylor is “interchangeable” with the funnel structure of Fenwick. Applicants disagree. Other than the unsupported conclusion of interchangeability, the Office action fails to identify any suggestion or motivation that indicates that the funnel of Fenwick could be replaced by the pouch of Taylor, or that the pouch of Taylor could be used in place of the funnel of Fenwick.

To the contrary, the funnel does not seem to be simply “interchangeable” with a pouch. The drape that Taylor describes is used for arthroscopy procedures. Column 4, lines 59-63, states, “...the detailed description hereinbefore relates the use of the new surgical drape in connection with the performance of an operation on a patient’s knee,” . . . “is equally applicable to other arthroscopic procedures.” Arthroscopic procedures relate to those performed on a *joint*. The Taylor drape has a fundamentally different use than the Fenwick drape, and is used in a fundamentally different manner than the Fenwick drape and on a different position on the body. As noted above, the Taylor drape is illustrated as being positioned vertically on a single leg, whereas the Fenwick drape is extended between a patient’s two horizontal legs. Based on these different applications, and the different orientations of the drapes, pouch, and funnel, the funnel and pouch are not simply interchangeable. For example, the use of a vertical pouch and drape as shown by Taylor would be potentially inconsistent with the overall description of Fenwick, which includes a drape that extends horizontally between a patient’s two legs.

The Office action fails to identify any suggestion or motivation within the prior art that would have led one of skill to the subject matter of claim 40, e.g., that would have motivated one of skill to replace the funnel of Fenwick with a pouch. Without a showing of such a motivation, the outstanding rejection of claim 40 is not supported and can be considered to be a hindsight reconstruction of Applicants’ claimed subject matter. The rejection of claim 40, reciting the subject matter of claim 2, should therefore be withdrawn.

Conclusion

In the outstanding Office Action, Claim 8 was objected to as being depending upon a rejected base claim. Claim 8 has been rewritten in independent form as independent claim 41, which includes all of the features of the base claim.

Claims 16-39 were allowed.

Applicants submit that the claims in their amended forms overcome the asserted rejections. Applicants believe that patentability extends to all of the pending claims. In view of the present amendments and remarks provided herein, Applicants submit that the

rejections have been either overcome or should otherwise be withdrawn, and request that a notice regarding the allowability of all pending claims be issued.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

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